REMARKS

Formal Matters

Claims 1, 2, 4, 5 and 7 are pending after entry of the amendments set forth herein.

Claims 1-5 and 7 were examined and rejected.

Claim 1 is amended. The amendment is made solely in the interest of expediting prosecution, and is not to be construed as an acquiescence to any objection or rejection. Support for the amendment to claim 1 is found in claim 3 as originally filed. Accordingly, no new matter is added.

Claims 3, 6 and 8-34 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Claim objection

Claim 1 is objected to for reciting the word "redue".

Claim 1 has been amended to recite the word "reduce".

The Applicants respectfully submit that this objection has been adequately addressed and may be withdrawn.

Rejection under 35 U.S.C. §112, first paragraph (written description)

Claims 1-5 and 7 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicants respectfully traverse this rejection.

The rejected claims are directed to a method of reducing the grown of a cancerous cell. The claimed methods employ a TTK antisense polynucleotide. The Office argues

that TTK antisense polynucleotides are not adequately described in the instant specification, and, as such, the claimed method is not adequately described.

The standard for written description has been established over several years of court cases such as *Vas-Cath* Inc. *v. Mahurkar*[1] and *In re Wertheim*[2] and has culminated in the publication of the "Written Description Guidelines" Federal Register Vol. 66 No. 4, dated January 5, 2001, to which the Office ***must*** adhere when making a written description determination. For training of Office personnel, the Office has also published the "Revised Interim Written Description Guidelines Training Materials" (published to the world wide website of the U.S. Patent and Trademark Office on March 1st, 2000 and termed hereinafter the "Training Materials"). The URL of the entire Training Materials is http://www.uspto.gov/web/offices/pac/writtendesc.pdf. For the Examiner's convenience, Example 15 of the Training Materials is attached hereto as Exhibit A.

Example 15 of the Training Materials describes a scenario that is almost identical to that currently under examination. In summary, Example 15, entitled "Antisense", provides an example of a specification that discloses SEQ ID NO: 1 (encoding human growth hormone) and a claim to a SEQ ID NO:1 antisense molecule.

In this example, only SEQ ID NO:1 is described with a complete structure.

The Training Materials states that the claimed antisense molecules of Example 15 are adequately described by the specification because: a) SEQ ID NO:1 defines and limits the structure of antisense molecules such that one of skill in the art would be able to immediately envision members of the genus recited in the claim; and, b) methods of screening for and making antisense molecules are routine. The Training Materials concludes by stating that the claimed antisense molecules meet the requirements of 35 USC §112 first paragraph.

For the same reasons, i.e., because the sequence of TTK defines and limits the structure of TTK antisense molecules and because methods of screening for and making

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[1] *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

[2] *In re Wertheim* 191 U.S.P.Q. 90 (C.C.P.A. 1996)

antisense molecules are routine, the TTK antisense molecules of the rejected claims should be considered adequately described.

According to the Office's own guidelines therefore, the rejected claims meet the written description requirements of 35 USC §112, first paragraph.

In view of the foregoing, the Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. §112, first paragraph (enablement)

Claims 1-5 and 7 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicants respectfully traverse this rejection.

The first sentence of ¶20 of the Office Action states that the specification is enabling for the inhibition of cancer cell grown *in vitro*.

Without any intention to acquiesce to this rejection and solely to expedite prosecution, claim 1 has been amended to recite a "cancerous cell *in vitro*".

The Applicants respectfully submit that this rejection has been adequately addressed. Withdrawal of this rejection is respectfully requested.

The Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number 2300-16932.

Respectfully submitted,

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10/081,119 Exhibit A

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

Example 15: Antisense

Specification: The specification discloses a messenger RNA sequence, SEQ ID NO: 1, which encodes human growth hormone. The specification states that the invention includes antisense molecules that inhibit the production of human growth hormone. The specification describes an art-recognized method of screening for antisense molecules that is called "gene walking." Gene walking is said to involve obtaining antisense oligonucleotides that are complementary to the target sequence.

Claim:

An antisense oligonucleotide complementary to a messenger RNA having SEQ ID NO: 1 and encoding human growth hormone, wherein said oligonucleotide inhibits the production of human growth hormone.

Analysis:

A review of the full content of the specification indicates that the complement of SEQ ID NO: 1 is essential to the operation of the claimed invention. The general knowledge in the art is that any full-length complement of a target mRNA inhibits the function of the mRNA and is therefore an antisense oligonucleotide. Thus, one of skill in the art would view applicant's disclosure of a coding sequence, with the statement that the invention includes antisense oligonucleotides, as an implicit disclosure that the full-length complement of SEQ ID NO: 1 is an antisense oligonucleotide.

It is generally accepted in the art that oligonucleotides complementary to a messenger RNA, including fragments of the full-length complement, have antisense activity when they match accessible regions on the target mRNA. Generally, the closer the complementary fragment is to full length, the greater the likelihood it will have antisense activity. In addition, oligos that retain complementarity to the Shine-Delgarno sequence usually have antisense activity.

The claim is drawn to the genus of antisense molecules that inhibit the production of human growth hormone encoded by SEQ ID NO: 1. There is a single species described with a complete structure, i.e., the full-length complement of SEQ ID NO: 1. In addition to the full-length complement, the genus includes fragments of the complement that retain antisense activity.

The procedures for making oligonucleotide fragments of the SEQ ID NO: 1 complement are conventional, e.g., any specified fragment can be ordered from a commercial synthesizing service. The procedures for screening for antisense activity are also conventional, and the specification describes the assay needed to do gene walking. The experience accumulated in the art with gene walking is that numerous regions of a target are accessible, that these regions are identified routinely, and that antisense oligonucleotides are complementary to these accessible regions. The full-length complement and longer fragments match multiple accessible regions; shorter fragments match fewer accessible regions.

When considering the distinguishing characteristics of the claimed invention, the sequence provided in the specification defines and limits the

structure of any effective antisense molecules. The specification also teaches the functional characteristics of the claimed invention as well as a routine art recognized method of making and screening for the claimed invention. Considering the specification's disclosure of:

(1) the sequence (SEQ ID NO: 1) which defines and limits the structure of any effective antisense molecules such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim, and

(2) the functional characteristics of the claimed invention as well as a routine art-recognized method of screening for antisense molecules which provide further distinguishing characteristics of the claimed invention, along with

(3) the general level of knowledge and skill in the art,

one skilled in the art would conclude that applicant was in possession of the invention.

Conclusion: The claimed invention is adequately described.